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PATENT EXTENSION
A/C PATENTS

Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1-23, 12420 Parklawn Drive
Rockville, Maryland 20857

RE: Docket No.: 95E-0302, Federal Register
Volume 60, No 235/Thursday Dec 7, 1995/page 62869

Dear Sirs:

The Drug Price Competition and Patent Term Restoration Act of 1984 provides that a patent may be extended to patented items defined as human drug products, animal drug products, medical devices, food additives, and color additives.

On the basis of this Act, an application has been made to the Patent and Trademark Office by Baxter International for an extension to Ultane™ (U.S. Patent No. 4,250,334). The patent was issued on Feb 10, 1981 to inventors Clifford L. Coon and Robert L. Simon and assigned to Baxter Travenol Laboratories Inc.

It should be noted that this patent does not claim any of the items defined in the Patent Term Restoration Act of 1984. The patent in question (U. S. 4,250,334) is a process patent. All of the sixteen claims of the patent are related to a method for the synthesis or manufacture of "Ultane ™". There are no claims for this compound either as a composition of matter or for its use as an anesthetic agent. Ultane ™ was claimed previously as both a composition of matter and its use as an anesthetic agent in the following patents:

COMPOSITION OF MATTER PATENT
U. S. Patent No. 3,527,814 issued on Sept 8, 1970 to Louise S. Croix and Alex J. Szur, the inventors and assigned to Air Reduction Co.

ANESTHETIC USE PATENT
U. S. Patent No. 3,683,092 issued on August 8, 1972 to Bernard M. Regan and John C. Longstreet, the inventors and assigned to Baxter Laboratories Inc.

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We believe that the determination of a Regulatory Review Period for the purpose of Patent Extension of U. S. Patent 4,250,334 is not appropriate since the patent does not claim a human drug product but rather claims only a method of chemical synthesis.

We believe that the appropriate action would be for the Food and Drug Administration to advise the Commissioner of Patents that the application for extension of this patent does not apply and that the determination of the regulatory review period is not necessary since the application for extension is not within the scope of the Patent Term Restoration Act of 1984.

Yours sincerely,

Ross C. Terrell

Ross C. Terrell, PhD.
Vice President of Research and Development